

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF
OBSTETRICIANS AND
GYNECOLOGISTS, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Case No. 8:20-cv-1320-TDC

MOTION TO INTERVENE

Pursuant to Rule 24 of the Federal Rules of Civil Procedure, the States of Indiana, Louisiana, Alabama, Arkansas, Idaho, Kentucky, Mississippi, Missouri, Nebraska, and Oklahoma respectfully move to intervene in this matter for the purpose of defending the constitutionality of the Mifepristone In-Person Dispensing Requirement as applied during the COVID-19 pandemic. In support of this Motion, the State asserts as follows:

1. On May 27, 2020, Plaintiffs filed this lawsuit challenging the Mifepristone In-Person Dispensing Requirement of the FDA REMS. On the same day, Plaintiffs also filed a motion for preliminary injunction. Responses to the preliminary injunction motion are due June 10, 2020.
2. Intervenor States meet the requirements for intervention as of right under Rule 24(a): this motion is timely, the States have a direct and substantial interest in the litigation, their interest will be impaired if it is not allowed to intervene, and the FDA will not adequately represent their interest.
3. In particular, Indiana Code section 16-34-2-1 directly invokes the FDA REMS. It provides: “In accordance with the FDA guidelines, the physician shall provide the pregnant

woman with a copy of the manufacturer's instruction sheets and require that the pregnant woman sign the manufacturer's patient agreement form." *Id.* The statute specifically provides that "'in person' does not include the use of telehealth or telemedicine services." *Id.* Because Indiana Code section 16-34-2-4 directly implicates the FDA REMS, its enforceability will be called into question if the REMS are enjoined.

4. Indiana and all Intervenor States have statutes that, like the FDA regulations, require mifepristone to be dispensed in person. Therefore, Intervenor States has an interest in defending the REMS in this case.

5. Intervenor States also have a strong interest in protecting their citizens from the health and safety consequences that may result from unsupervised administration of mifepristone. Mifepristone can have serious complications, including hemorrhaging, infection, and even death. These complications can be exacerbated if the physician does not perform an in-person examination. An in-person meeting also facilitates informed consent and prevents the diversion of drugs and mitigates the possibility of complications, which may in turn yield Medicaid claims.

6. These interests will be impaired if the States are not allowed to intervene in this case. Without intervention, Intervenor States will be less able protect its citizens from the dangers of mifepristone and will be forced to expend more Medicaid funding to treat the complications that result.

7. Finally, the FDA will not adequately represent Intervenor States' interests because it does not share the State's broader interests in protecting the welfare of its citizens, preventing the diversion of drugs, and preventing human trafficking. In particular, the state intends to submit expert and other testimony supporting the REMS that is not available in the administrative record, and FDA may not submit any additional testimony.

8. In the alternative, Intervenor States should be permitted to intervene under Rule 24(b)(1) because their statutes require mifepristone to be dispensed in person, and thus, they share a common question of law with the challenge to the FDA in-person requirement.

For the foregoing reasons, the Court should grant the States' motion to intervene in this case.

Dated: June 8, 2020

Respectfully submitted,

/s/ Alexander A. Bush

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* *Pro Hac Vice Motion Pending*

Counsel for Movant States

CERTIFICATE OF SERVICE

I hereby certify that on June 8, 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Alexander A. Bush

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